

**REMARKS**

Claims 32-43, 46, 47 and 49-62 are currently pending. Claims 32-39 and 49-62 have been withdrawn as being directed to a non-elected invention. Applicant respectfully reserves the right to file divisional applications directed to the non-elected subject matter. Claim 40 has been amended to require the first patch to be a topical analgesic patch that applies a first analgesic therapy to the portion of the body when the first patch engages the portion of the body. Support for this amendment may be found, for example, in paragraphs [0027] and [0038] of the specification of the published application (U.S. 2005/0042267 A1). Claim 42 has been amended to require the third patch to be an exothermic heating patch. Support for this amendment may be found, for example, in paragraph [0030] of the specification of the published application. No new matter has been added by these amendments.

**I. Rejections under 35 U.S.C. § 103(a)**

Reconsideration is requested of the rejection of claims 40, 41, 43, 46 and 47 under 35 U.S.C. § 103(a) as being unpatentable over Westplate (U.S. 4,592,358) in view of either Kanios, et al. (U.S. 6,905,016) or Sudsina, et al. (U.S. 6,004,345).

Claim 40 is directed to a system for providing therapy to a portion of the body. The system comprises:

- a container that includes at least one compartment;
- a first patch held by said container, wherein said first patch is a topical analgesic patch and applies a first analgesic therapy to the portion of the body when said first patch engages the portion of the body;

a second patch held by said container, wherein said second patch applies a second therapy to the portion of the body when said second patch engages the portion of the body, the second therapy being different than the first therapy; and

a flexible wrap held by said container, the flexible wrap being adapted to secure at least one of said first patch and said second patch to the portion of the body, wherein the first patch, the second patch and the flexible wrap are all within the same compartment in the container.

Westplate is directed to a therapeutic device featuring a plurality of compartments enclosing a therapeutic substance. The therapeutic substance can be a refrigerant material or a heat releasing substance. The therapeutic device may be encircled or conformed to a portion of the body. Further, packets of variable weights may be accommodated in the compartments of the therapeutic device in order to compress an injured area while simultaneously heating or cooling the area.

Significantly, however, as recognized by the Office on page 13 of the instant Office action, Westplate does not describe or suggest using an analgesic patch. Moreover, on page 5 of the instant Office action, the Office also recognizes that Westplate does not disclose or suggest placing the packets and the therapeutic device all within the same compartment in a container. Recognizing the deficiencies of Westplate, the Office cites either Kanios, et al. or Sudsina, et al. for combination with Westplate in an attempt to arrive at each and every limitation of Applicant's claim 40.

Kanios, et al. (hereinafter "Kanios") discloses a transdermal delivery system. The system includes a product packaging system to prevent or control degradation reactions that can result from certain packaging materials and moisture

contamination while providing a child-resistant wrapping for the transdermal system. The packaging system includes a primary layer and a secondary layer held together by an adhesive material that form the pouch. The pouch can contain multiple packages of a transdermal drug. The transdermal drug can be methylphenidate.

Sudsina, et al. (hereinafter "Sudsina") disclose a therapeutic wrap for sore throats. The therapeutic wrap can be placed in a kit with a vaporizing ointment. The wrap helps to keep the user's neck and chest warm so that the vaporizing ointment can have its maximum effect.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. § 2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the Graham factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited references fail to show each and every limitation of Applicant's invention and there is no apparent reason for one skilled in the art to modify/combine the references to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicant's claimed

combinations.

Initially, Applicant notes that the combination of Westplate with either Kanios or Sudsina is not used to reject Applicant's claim limitations that require one of the patches to be a topical analgesic patch. That is, in the previous Office action (mailed July 8, 2010), the Office required the Zhang reference in combination with Westplate and either Kanios or Sudsina in order to reject Applicant's claim limitations that required a topical analgesic patch. As such, the Office recognizes that a system for providing therapy to a portion of a body wherein a first patch is a topical analgesic patch that applies a first analgesic therapy to the portion of the body when the first patch engages the portion of the body and the first patch is held in a container along with a second patch (that provides a different therapy than the first patch) and a flexible wrap is patentable over the combination of Westplate and either Kanios or Sudsina.

Moreover, Applicant maintains that the combination of cited references fails to disclose or suggest a system comprising a first patch, a second patch and a flexible wrap all within the same compartment in a container, wherein the second patch and the first patch apply different therapies to the body, as is required in Applicant's claim 40. This is a significant aspect of Applicant's invention, as the system allows a user or therapist to conveniently apply one or more alternative therapies to an injured portion of a body (see, e.g., para. [0011] of the published application (U.S. 2005/0042267 A1)).

Instead, at best, the combination of cited references discloses placing a patch and/or packet, with a single therapy, in a container. In particular, as noted by the Office, Westplate discloses packets that provide more than one therapy

(such as heating or cooling), however, the packets are individually placed in the compartments of Westplate, and are not placed in the compartments together, or, with a flexible wrap, as the flexible wrap in Westplate is the container. Similarly, though Kanios discloses a packaging system that can have multiple packets in one pouch, the packets all contain a single therapy. Further, though Sudsina discloses a vaporizing ointment in the same container as a flexible wrap, again, the vaporizing ointment is a single therapy, and there is no disclosure in Sudsina of a flexible wrap in the same container with two different therapies, as is required in Applicant's claim 40. Thus, nowhere does either the combination of Westplate and Kanios or the combination of Westplate and Sudsina ever disclose a container that holds a flexible wrap and a first and second patch, wherein the first and second patch provide different therapies to a user of the system, within the same compartment. As such, the combination of cited references fails to provide a *prima facie* case of obviousness because the combination of cited references fails to disclose each and every limitation of Applicant's claim 40.

Further, as noted above, the Office already acknowledges that there is no apparent reason to modify/combine the cited references in order to arrive at a system including a first patch being a topical analgesic patch as required in Applicant's amended claim 40. Accordingly, it should be recognized that amended claim 40 is not obvious in view of the combination of Westplate and either Kanios or Sudsina.

For the reasons set forth above, the combination of cited references fails to disclose or suggest each and every element of Applicant's claim 40, and, further, there is no articulated reason to modify/combine the cited references in order to arrive

at the specific system for providing therapy to a portion of a body as disclosed in Applicant's claim 40. Accordingly, claim 40 is patentable over the combination of cited references.

Claims 41, 43, 46 and 47 depend from claim 40 and are thus patentable over the combination of cited references for the same reasons set forth above with respect to claim 40, as well as for the additional elements they require.

## **II. Rejections under 35 U.S.C. § 103(a)**

Reconsideration is requested of the rejection of claim 42 under 35 U.S.C. § 103(a) as being unpatentable over Westplate (U.S. 4,592,358) in view of either Kanios, et al. (U.S. 6,905,016) or Sudsina, et al. (U.S. 6,004,345) as applied to claims 40, 41, 43, 46 and 47 above, and further in view of Zhang, et al. (U.S. 6,245,347).

Claim 42 depends from claim 40, which is discussed above.

Westplate, Kanios and Sudsina are discussed above. As noted above, the combination of Westplate and Kanios and/or the combination of Westplate and Sudsina fails to disclose each and every element of Applicant's amended claim 40. Recognizing the deficiencies of the cited references, the Office cites Zhang, et al. in combination with the cited references in an attempt to arrive at each and every element of Applicant's claim 42.

Zhang, et al. (hereinafter "Zhang") disclose methods and an apparatus for improving administration of drugs through the use of heat and other physical means. The drugs can be delivered into a sub-skin depot site via injection and other methods to alter, mainly increase, the drug release rate from the dermal drug delivery systems or the depot sites to accommodate certain clinical needs.

Significantly, similar to the references cited above, Zhang fails to disclose or suggest a system wherein a first patch and a second patch that provide different therapies being held with a flexible wrap within the same compartment in a container. As such, the combination of cited references fails to disclose or suggest each and every element of Applicant's claim 40. That is, though Zhang discloses a dermal drug delivery system and a temperature control apparatus, the dermal drug delivery system and the temperature control apparatus are stored in separate compartments and not with a flexible wrap inside of a container. As such, the combination of cited references fails to disclose or suggest a system for providing therapy to a portion of the body wherein a first topical analgesic patch and a second patch that applies a different therapy are held with a flexible wrap in the same container.

Further, there is no articulated reason to modify/combine the cited references in order to arrive at the specific system for providing therapy to a portion of a body as required in Applicant's claim 40. On page 13 of the instant Office action, the Office states that it would have been obvious to combine the cited references because "Westplate desired to treat injured parts of the body that may need analgesia." Applicant respectfully disagrees.

Specifically, as noted above, neither Westplate nor Zhang disclose a container that holds a flexible wrap and a first patch and a second patch with different therapies within the same compartment. In fact, if anything, Zhang actually teaches away from having the dermal drug delivery system in a compartment with a heating or cooling mechanism. That is, Zhang expressly teaches that the temperature control apparatus and the dermal drug delivery system are preferably stored in separate

compartments of the container.<sup>1</sup> As such, why would one having ordinary skill in the art look to place the temperature control apparatus and the dermal drug delivery system of Zhang within the same compartment? It simply cannot be stated that it would be obvious to do so.

In order to arrive at the specific system for providing therapy to a portion of a body as described in Applicant's claim 40, one would have to first: (i) enclose the device of Westplate in a container as taught by Kanios in order to protect the patches of Westplate from moisture contamination and environmental factors, when Westplate already provides for such a means through the use of a double layer of durable, flexible, liquid impervious material; or (ii) combine the teachings of Westplate with Sudsina so that the packages and wrap could be conveniently stored together, when Sudsina does not disclose or recognize the importance of having different therapies and a flexible wrap stored together within the same compartment of a container. Then, one having ordinary skill in the art would have to further look to Zhang to require one of the patches within the compartment to be a topical analgesic patch that provides a different therapy than the second patch that is held within the same compartment. One would have to make these combinations/modifications without any guidance from the cited references, when nowhere does the combination of cited references ever disclose or suggest such as system. Again, it appears that the Office is using Applicant's disclosure as a blueprint to impermissibly pick and choose elements from the prior art in an attempt to arrive at the specific system of Applicant's claim 40. As previously argued, such hindsight reconstruction and analysis is prohibited. Accordingly,

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<sup>1</sup> Zhang, et al., column 12, lines 5-9.



Applicant submits that claim 40 is patentable over the combination of cited references.

Claim 42 depends from claim 40 and is thus patentable over the combination of cited references for the same reasons set forth above with respect to claim 40, as well as for the additional limitations it requires.

**CONCLUSION**

For the reasons stated above, Applicant respectfully requests that the Examiner's rejections be reversed and that the pending claims be allowed. The Commissioner is hereby authorized to charge any fees which may be required to Deposit Account Number 01-2384.

Respectfully Submitted,

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Via EFS